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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,735	06/15/2001	Eric F. Fisher	02,006; A-415H	1579

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
09/882,735	FISHER ET AL.	
Examiner	**Art Unit**	
Eileen B. O'Hara	1646	

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   A. Claims 1-12, 22-25, 28 and 31, drawn to truncated sTNFR polypeptides, classified in class 530, subclass 350.

   B. Claims 7-12, 23, 28 and 31 drawn to polyvalent sTNFR polypeptides, classified in class 530, subclass 421, for example.

   C. Claims 13-21, drawn to polynucleotides encoding truncated sTNFR polypeptides, vectors, host cells and method of recombinantly producing protein, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

   D. Claims 26, 27, 29 and 30, drawn to a method for treating a TNF-mediated disease comprising administering a truncated sTNFR polypeptide, classified in class 514, subclass 12.

2. The inventions are distinct, each from the other because of the following reasons:

   Inventions A and B are related in that the polyvalent polypeptides of invention comprise the polypeptides of invention A, but the polyvalent polypeptides contain more than one polypeptide sequence and are chemically modified, resulting in different structure and function from the polypeptides of invention A.

   Inventions A and B are each related to invention C are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide is related to the polypeptide by virtue of encoding the same. The polynucleotides have utility for the recombinant production of protein in a host cell. Although the polynucleotides and proteins are related since the polynucleotides encode the specifically claimed proteins, they are distinct inventions because the protein products can be made by another materially different process, such as by synthesis or purification from the natural source. Further, the polynucleotides may be used for processes other than the production of proteins, such as nucleic acid hybridization assays and gene therapy.

Each of inventions A and B are related to invention D as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides and polyvalent polypeptides can be used in the method of treatment of invention D, but the polypeptides and polyvalent polypeptides can also be used in a method of generating antibodies, which is a materially different method.

Inventions C and D are related as process of making and process of using a common product. The polynucleotides encode the polypeptides which are used in the method of treatment of invention D, but the polynucleotides can also be used in a method hybridization, which is a materially different method.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Further Restriction Within Groups A, B and D

3. If Groups A, B or D is elected, further restriction *within* the elected group is required, as follows: sTNFR polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14 or 16.

Further Restriction Within Group C

4. If Group C is elected, further restriction *within* the group is required, as follows: polynucleotide encoding sTNFR polypeptide of SEQ ID NO: 2, 4, 6, 8, 10, 12, 14 or 16.

Applicant is advised that this is not a species election.

Although the classifications these various nucleic acids, proteins, and methods of use are overlapping, for instance 536/23.1 or 530/350, each represents a patentably distinct product, with different sequences and structures and with distinct physical and functional characteristics. Further, the search for more than one product would be burdensome, because each sequence would require a separate search. Accordingly, restriction is proper.

This requirement might be withdrawn if Applicants could demonstrate that the proteins are not patentably distinct and would not require separate searches.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Species Elections

5.1 If the polypeptide of SEQ ID NO: 2 is elected (or polynucleotide encoding), there is a further requirement of a species election. This application contains claims directed to the following patentably distinct species of the claimed invention: the specific truncations of the polypeptide of SEQ ID NO: 2 that are listed in claim 1. Applicant is required to elect one specific truncation.

5.2 If the polypeptide of SEQ ID NO: 16 is elected (or polynucleotide encoding), there is a further requirement of a species election. This application contains claims directed to the following patentably distinct species of the claimed invention: the specific truncations of the polypeptide of SEQ ID NO: 16 that are listed in claim 3. Applicant is required to elect one specific truncation.

5.3 If Group D is elected, there is a further requirement of a species election. Claims 26 and 29 are generic to a plurality of disclosed patentably distinct species comprising TNF-mediated disease. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of TNF-mediated disease from those listed for example on pages 67-70 and 73, 74, 84 and 89, even though this requirement is traversed. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or

otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). Currently, claims 26 and 29 are generic for TNF-mediated disease.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600